

Nuclear Regulatory Commission

§ 35.604

for ophthalmic radiotherapy. The training must include—

- (i) Radiation physics and instrumentation;
- (ii) Radiation protection;
- (iii) Mathematics pertaining to the use and measurement of radioactivity; and

- (iv) Radiation biology; and

(2) Supervised clinical training in ophthalmic radiotherapy under the supervision of an authorized user at a medical institution, clinic, or private practice that includes the use of strontium-90 for the ophthalmic treatment of five individuals. This supervised clinical training must involve—

- (i) Examination of each individual to be treated;
- (ii) Calculation of the dose to be administered;
- (iii) Administration of the dose; and
- (iv) Follow up and review of each individual's case history; and

(3) Has obtained written certification, signed by a preceptor authorized user who meets the requirements in §§ 35.490, 35.491, or, before October 24, 2004, §§ 35.940 or 35.941, or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in paragraphs (a) and (b) of this section and has achieved a level of competency sufficient to function independently as an authorized user of strontium-90 for ophthalmic use.

[67 FR 20370, Apr. 24, 2002, as amended at 68 FR 19326, Apr. 21, 2003]

Subpart G—Sealed Sources for Diagnosis

§ 35.500 Use of sealed sources for diagnosis.

A licensee shall use only sealed sources for diagnostic medical uses as approved in the Sealed Source and Device Registry.

§ 35.590 Training for use of sealed sources for diagnosis.

Except as provided in § 35.57, the licensee shall require the authorized user of a diagnostic sealed source for use in a device authorized under § 35.500 to be a physician, dentist, or podiatrist who—

(a) Is certified by a specialty board whose certification process includes all of the requirements in paragraph (b) of this section and whose certification has been recognized by the Commission or an Agreement State; or

(b) Has had 8 hours of classroom and laboratory training in basic radionuclide handling techniques specifically applicable to the use of the device. The training must include—

- (1) Radiation physics and instrumentation;
- (2) Radiation protection;
- (3) Mathematics pertaining to the use and measurement of radioactivity;
- (4) Radiation biology; and
- (5) Training in the use of the device for the uses requested.

Subpart H—Photon Emitting Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units

§ 35.600 Use of a sealed source in a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit.

A licensee shall use sealed sources in photon emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units for therapeutic medical uses:

(a) As approved in the Sealed Source and Device Registry; or

(b) In research in accordance with an active Investigational Device Exemption (IDE) application accepted by the FDA provided the requirements of § 35.49(a) are met.

§ 35.604 Surveys of patients and human research subjects treated with a remote afterloader unit.

(a) Before releasing a patient or a human research subject from licensee control, a licensee shall survey the patient or the human research subject and the remote afterloader unit with a portable radiation detection survey instrument to confirm that the source(s) has been removed from the patient or human research subject and returned to the safe shielded position.

(b) A licensee shall retain a record of these surveys in accordance with § 35.2404.